

CLAIMS

1. A method for diagnosing a disease condition characterized by non-physiological levels of hepcidin, comprising obtaining a tissue or fluid sample from a subject; contacting the sample with an antibody or fragment thereof that specifically binds to one or more mid-portion or carboxy terminal epitopes of hepcidin, and quantifying hepcidin level in the sample; wherein the non-physiological level of hepcidin is indicative of the disease condition.

10 2. The method of claim 1, wherein the antibody specifically binds a mid-portion epitope contained within amino acids 28 to 47 of hepcidin.

15 3. The method of claim 1, wherein the antibody specifically binds a carboxy terminal epitope contained within amino acids 70 to 84 of hepcidin.

20 4. The method of claim 1, wherein the quantifying comprises conducting an assay selected from the group consisting of a radioimmunoassay, an enzyme-linked immunosorbant assay, a sandwich assay, a precipitin reaction, a gel immunodiffusion assay, an agglutination assay, a fluorescent immunoassay, a protein A immunoassay and an immunoelectrophoresis assay.

25 5. A kit for detecting a disease condition characterized by non-physiological levels of hepcidin, comprising, an anti-hepcidin antibody or fragment thereof that specifically binds to one or more mid-portion or carboxy terminal epitopes of hepcidin, and a reagent that binds directly or indirectly to the antibody or fragment thereof.

6. The kit of claim 5 wherein the anti-hepcidin antibody or fragment thereof is immobilized on a support.

30 7. The kit of claim 5 wherein the reagent comprises hepcidin complexed with a first binding molecule.

8. The kit of claim 7 wherein the first binding molecule is biotin.

9. The kit of claim 8 wherein the kit further comprises an enzyme complexed with a second binding molecule and a substrate of
5 the enzyme.

10. The kit of claim 9, wherein the second binding molecule is streptavidin.

11. The kit of claim 9, wherein the enzyme is horse radish peroxidase, and the substrate comprises peroxide.

10 12. An antibody or fragment thereof that specifically binds to one or more mid-portion or carboxy terminal epitopes of hepcidin.

13. The antibody of claim 12, wherein the mid-portion epitope is contained within amino acids 28 to 47 of hepcidin.

15 14. The antibody of claim 12, wherein the carboxy terminal epitope is contained within amino acids 70 to 84 of hepcidin.

15 15. The method of claim 1, wherein said hepcidin comprises pro-hepcidin, hepcidin or fragments thereof.

16. The method of claim 1, wherein said hepcidin comprises
20 pro-hepcidin.

17. The kit of claim 5, wherein said hepcidin comprises pro-hepcidin or hepcidin.

18. The kit of claim 5, wherein said hepcidin comprises pro-hepcidin.

25 19. The hepcidin of claim 12, wherein said hepcidin comprises pro-hepcidin or hepcidin.

20. The hepcidin of claim 12, wherein said hepcidin comprises pro-hepcidin.